Complete Summary

GUIDELINE TITLE

Staging laparoscopy for biliary tract tumors. In: Diagnostic laparoscopy guidelines.

BIBLIOGRAPHIC SOURCE(S)

Staging laparoscopy for biliary tract tumors. In: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Diagnostic laparoscopy guidelines. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2007 Nov. p. 51-4.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). SAGES guidelines for diagnostic laparoscopy. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2002 Mar. 5 p.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Biliary tract tumors:

- Gallbladder cancers
- Cholangiocarcinomas

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Gastroenterology
Oncology
Radiology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To assist surgeons' decisions about the appropriate use of staging laparoscopy in patients with biliary tract tumors
- To update the previous 2002 guidelines on this topic

TARGET POPULATION

Patients with:

- Known or suspected gallbladder cancer without evidence of unresectable or metastatic disease
- Stage T2 or T3 hilar cholangiocarcinoma without evidence of unresectable or metastatic disease determined by preoperative imaging

INTERVENTIONS AND PRACTICES CONSIDERED

Staging laparoscopy in patients with biliary tract tumors

MAJOR OUTCOMES CONSIDERED

- Procedure-related/intraoperative complications
- Procedure-related morbidity
- Time to adjuvant treatment
- Adverse oncologic effects
- Mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A systematic literature search of MEDLINE for the period 1995-2005 was limited to English language articles. The search strategy is shown in Figure 1 in the original guideline document. Using the same strategy, the Cochrane database of evidence-based reviews and the Database of Abstracts of Reviews of Effects (DARE) were searched.

Abstracts were reviewed by three committee members and into the following categories:

- Randomized studies, meta-analyses, and systematic reviews
- Prospective studies
- Retrospective studies
- Case reports
- Review articles

Randomized controlled trials, meta-analyses, and systematic reviews were selected for further review along with prospective and retrospective studies that included at least 50 patients; studies with smaller samples were reviewed when other available evidence was lacking. The most recent reviews were also included. All case reports, old reviews, and smaller studies were excluded.

The reviewers graded the level of evidence of each article and manually searched the bibliographies for additional articles that may have been missed by the search. Any additional relevant articles were included in the review and grading.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
Level II	Evidence from controlled trials without randomization Or Cohort of case-control studies Or Multiple time series, dramatic uncontrolled experiments

Level III	Descriptive case series, opinions of expert panels

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

To maximize the efficiency of the review, articles were divided into three subject categories:

- Staging laparoscopy for cancer
- Diagnostic laparoscopy for acute conditions
- Diagnostic laparoscopy for chronic conditions

Reviewers graded the level of each article (see "Rating Scheme for the Strength of the Evidence.")

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines were developed under the auspices of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and revised by the SAGES Guidelines Committee.

The statements included in this guideline are the product of a systematic review of published work on the topic, and the recommendations are explicitly linked to the supporting evidence. The strengths and weaknesses of the available evidence are described and expert opinion sought where the evidence is lacking. This is an update of previous guidelines on this topic (last revision 2002) as new information has accumulated.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Scale Used for Recommendation Grading

Grade A	Based on high-level (level I or II), well-performed studies with uniform interpretation and conclusions by the expert panel
Grade B	Based on high-level, well-performed studies with varying interpretation and conclusions by the expert panel
Grade C	Based on lower-level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

COST ANALYSIS

The literature was searched for cost analyses. There are no data in the literature addressing the cost-effectiveness of the procedure.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations of each guideline undergo multidisciplinary review and are considered valid at the time of production based on the data available. This statement was reviewed by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), November 2007.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (**I, II, III**) and the grades of the recommendations (**A, B, C**) are provided at the end of the "Major Recommendations" field.

General Recommendations for Diagnostic Laparoscopy

Diagnostic laparoscopy is a safe and well tolerated procedure that can be performed in an inpatient or outpatient setting under general or occasionally local anesthesia with intravenous sedation in carefully selected patients. Diagnostic laparoscopy should be performed by physicians trained in laparoscopic techniques who can recognize and treat common complications and can perform additional therapeutic procedures when indicated. During the procedure, the patient should be continuously monitored, and resuscitation capability must be immediately available. Laparoscopy must be performed using sterile technique along with meticulous disinfection of the laparoscopic equipment. Overnight observation may be appropriate in some outpatients.

Staging Laparoscopy (SL) for Biliary Tract Tumors

Technique

The patient is placed in the supine position, and pneumoperitoneum is established. A 30-degree laparoscope through an umbilical port is recommended for optimal visualization of the entire abdominal cavity. Additional ports can be placed in the right anterior axillary line and epigastric area as needed. Careful and thorough inspection of the peritoneum, pelvis, liver surfaces, porta hepatitis, gastrohepatic ligament, and omentum should be made. A standard laparoscopic ultrasound probe may improve the yield of finding lesions in the liver and lymph node metastasis in the porta and celiac nodal areas. Biopsy specimens of peritoneal metastases, nodes suspected to be malignant, or hepatic lesions should be obtained to determine the extent of disease.

Indications

- Known or suspected gallbladder cancer without evidence of unresectable or metastatic disease
- Stage T2 or T3 hilar cholangiocarcinoma without evidence of unresectable or metastatic disease determined by preoperative imaging

Recommendations

SL can be performed safely in patients with cancers of the biliary tract and gallbladder (**Grade B**). SL may be used for suspected gallbladder cancers that are believed to be resectable by preoperative, high quality imaging studies (**Grade B**). Patients with biliary tract cancers may also benefit from SL through the identification of imaging occult disease in the peritoneum, lymph nodes, or the liver itself (**Grade B**); the benefit of the procedure may be maximized in patients with locally advanced cholangiocarcinoma (stage T2 and T3), as the yield of the procedure in this patient population is higher (**Grade B**). Laparoscopic ultrasound may improve the yield of the procedure; however, additional data are needed regarding this (**Grade C**).

For details of the rationale for the procedure and its diagnostic accuracy, see the original guideline document.

Definitions:

Levels of Evidence

Level I	Evidence from properly conducted randomized, controlled trials
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Level III	Descriptive case series, opinions of expert panels

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Grade C	Based on lower-level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Staging laparoscopy may spare patients a laparotomy for incurable disease with an associated decreased morbidity and pain, faster recovery, and earlier time to adjuvant treatment.

POTENTIAL HARMS

- Procedure- or anesthesia-related complications (see "Procedure-related Complications and Patient Outcomes" section in the original guideline document)
- Unnecessary patient morbidity in cases of a low yielding procedure
- Potential adverse oncologic effects of the procedure
- False negative examinations that lead to unnecessary laparotomy

CONTRAINDICATIONS

CONTRAINDICATIONS

- Known metastatic or unresectable disease
- Known stage T1 disease found incidentally may potentially be treated with cholecystectomy alone

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by systematic review of available data and expert opinion. The approach suggested may not be the only acceptable approach given the complexity of the health care environment. These guidelines are intended to be flexible, as the surgeon must always choose the approach best suited to the patient and variables in existence at the time of the decision.

Limitations of the Available Literature

The reported literature for staging laparoscopy in biliary tract cancer patients is limited, and no level I evidence exists. There are a small number of reports from highly specialized centers with variations in technique. In addition, some studies span a period of 7-10 years, which likely affects the quality of preoperative imaging as well as laparoscopic technique at the beginning and end of the study. The impact of surgeon's expertise in the diagnostic accuracy of the procedure is unknown. These shortcomings of the literature limit the guideline developers' ability to provide strong recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Apr (revised 2007 Nov)

GUIDELINE DEVELOPER(S)

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

GUIDELINE COMMITTEE

Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) disclose potential conflicts of interest and pertinent financial relationships prior to serving as faculty for SAGES-sponsored educational events, delivering presentations at scientific meetings, etc. Additionally, members of SAGES Committees disclose their potential conflicts of interest and pertinent financial relationships annually as a condition of committee membership.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Web site.

Print copies: Available from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064; Web site: www.sages.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Patient information for diagnostic laparoscopy from SAGES. Available in English and Polish from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on November 19, 1999. The information was verified by the guideline developer on February 15, 2000. This summary was updated by ECRI on March 22, 2004. The information was verified by the guideline developer on April 27, 2004. This summary was updated by ECRI Institute on February 27, 2009. The updated information was verified by the guideline developer on March 9, 2009.

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